

ESWELL Newsletter

March 2020

Dear ESWELL customer,

I hope you have had a good start into the new year.

As in the previous years, we are sending out our Newsletter to inform you about product updates and other relevant topics.



Updated positioning pads

We are constantly working on improving our existing range of products based on feedback from you. This has resulted in the below changes to existing positioning pads.

In order to ensure better stability, we will change the foam construction of our **Leg positioning pad, bariatric** (Item no. 249151). In the future, it will have a base of foam with higher density and the usual soft viscoelastic foam covering it on top. Everything else will stay the same. We still have some pieces of the old version on stock. As soon as they are sold, we will start delivering the updated version.

Item no.	Description	Colour	Size L x W x H in mm	List price in EUR	
249151	Leg positioning pad, bariatric	Grey	650 x 500 x 140/109	538,15	

Simonsen & Weel A/S

Vejlegaardsvej 59
DK-2665 Vallensbaek Strand
Denmark
Tel. +45 70 25 56 10
Fax +45 70 25 56 20
E-mail: eswell@sw.dk
www.eswell.eu

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We have also updated our **Pad for arm support** (Item no. 248051). Some customers have complained that there needs to be a solution to secure the arm from sliding out of the pad. We have now solved this by adding a Velcro strap that can be attached and adjusted to fix the arm of the patient. Everything else will stay the same. The updated product will be on stock at the beginning of April.



Item no.	Description	Colour	Size L x W x H in mm	List price in EUR	
248051	Pad for arm support	Black	520 x 540 x 20	368,14	

New Medical Device Regulation

The new Medical Device Regulation (MDR 2017/745) will replace the existing Medical Device Directive (MDD 93/42/EEC) on May 26th, 2020. The new regulation is aimed at improving the traceability and safety of medical devices for sale within the EU. As a medical device Class I, all our ESWELL products need to be compliant with this new regulation.


For you as our distributor, the primary change will be the labelling on the product and on the packaging, and the need to ensure the above-mentioned traceability all the way to the end-user in your country.





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Within the next months, we will therefore introduce new labels on all standard products and packaging that will include the LOT no., the UDI (Unique Device Identification) code as well as a GS1 data matrix.







 Made in EU


 Simonsen & Weel A/S
 Vejlegaardsvej 59
 2665 Vallensbaek Strand
 Denmark

REF 249095
LOT 1908220416


 (01) 05712855000214
 (10) 1908220416

Discontinued products

Because of the new regulation, there will be some standard products that we have to eliminate from our range as these will **not** be covered by our Declaration of Conformity after May 26th, 2020. These are the following:

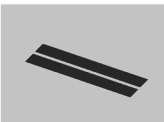
Item no.	Description	Colour	Size in mm	List price in EUR
248851	Velcro straps, hook	Black	50 wide	


Item no.	Description	Colour	Size in mm	List price in EUR
248852	Velcro straps, loop	Black	50 wide	


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Item no.	Description	Colour	Size in mm	List price in EUR	
213160	Nylon strap (pair)	Black	800 x 100 (400 mm velcro in the end)		

Item no.	Description	Colour	Size in mm	List price in EUR	
248144	Leg strap, nylon/velcro	Black	850 x 50 (300 mm velcro in both ends)		

Item no.	Description	Colour	Size in mm	List price in EUR	
248156	Leg straps, nylon	Black	2200 x 100		

If you intend to supply these products to your customers after May 26th, please make sure to order them as soon as possible, as we will not be able to ship these after the before mentioned date.

International exhibitions

If you are participating yourself at a congress/exhibition/meeting in your country, where you think that the participation of ESWELL could make a difference, let me know. I can join you at the exhibition and take with me our pressure imaging device in order to show how pressure changes when placing patients in different positions.

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